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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,461	09/30/2003	Ehud Dafni	393/03662	7538

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WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP
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EXAMINER

BAXTER, ZOE E

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,461

Applicant(s)

DAFNI, EHUD

Examiner

Zoe E. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 and 56-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,33,34,36-39,41-43,47,56,57,59,62-64 and 66 is/are rejected.
- 7) ☒ Claim(s) 32,35,40,44-46,58,60,61,65 and 67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/19/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 2 including claims 30-47 and new claims 56-67 in the reply filed on November 7, 2006 is acknowledged. The examiner further acknowledges the cancellation of claims 1-29 and 48-55. Claims 30-47 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 30, 31, 33, 34, 38, 39, 41-43, 56, 57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines et al. (US Patent No. 6152881) in view of Whitt et al. (US Patent no. 6309359 B1). Raines et al. teach an apparatus comprising:

- a. A measurement cuff adapted to apply a pressure to an artery (column 8 lines 52-53);
- b. A measurement unit adapted to determine, a value for a parameter of the artery, over one or more cardiac cycles, while the pressure is applied (column 9 lines 23-36);
- c. A controller adapted to apply to the cuff a pressure that causes the cross-sectional area of the artery to change between systole and diastole much more

than if the pressure is not applied, and to induce at least two measurement rounds of the parameter by the measurement unit while the pressure is applied (column 10 lines 8-27);

d. A processor adapted to compare the values determined by the measurement unit in the at least two measurement rounds (column 20 lines 19-39).

4. Raines et al. fail to teach an apparatus comprising a measurement unit wherein the value of the parameter is related to the cross-sectional area of the artery. Whitt et al. teach an apparatus comprising a measurement unit (column 8 lines 56-67) wherein the value of a measured parameter is related to cross sectional area of the artery (column 7 line 50-column 8 line 26). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Raines et al. to include a measurement parameter related to cross sectional area similar to that of Whitt et al. in order to better diagnose hypertension, peripheral arterial conditions and coronary arterial conditions (Whitt et al. Column 5 lines 1-4).

5. Referring to claim 31 Raines et al. teach an apparatus wherein the measurement cuff includes a hydraulic or pneumatic pump adapted to apply the pressure (column 9 lines 45-57).

6. Referring to claim 33 Raines et al. teach an apparatus wherein the processor is further adapted to determine a blood pressure, responsive to parameter values determined by the measurement unit (column 11 lines 64-66).

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7. Referring to claim 34 Raines et al. teach an apparatus wherein the cuff is adapted to apply the pressure substantially around an entire circumference of a limb including the artery (column 8 lines 43-67).

8. Referring to claim 38 Raines et al. teach an apparatus wherein the controller is adapted to induce at least one of the measurement rounds responsive to an indication that a stimulus (five minute occlusion period) was administered to the artery (column 11 lines 12-40) and at least one of the measurement rounds before the indication that the stimulus was administered to the artery is received (column 11 lines 64-66).

9. Referring to claim 39 Raines et al. teach an apparatus wherein the controller is adapted to apply the pressure continuously over at least five cardiac cycles of the patient (column 9 lines 1-9). Since the unit is applying pressure for a five minute interval it is therefor applying the pressure continuously over at least five cardiac cycles.

10. Referring to claim 41 Raines et al. teach an apparatus in which the controller is adapted to hold a pressure at a given value in order to measure the physiological condition of the blood pressure (column 12 lines 19-25). Raines et al. fail to teach the controller holds the pressure at the mean arterial pressure. Whitt et al teach that the mean arterial pressure is important in measuring the blood pressure (column 7 lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the controller of Raines et al. to include the mean arterial pressure as a significant pressure since Whitt et al teach that the mean arterial pressure is the pressure which corresponds to the maximum pulse size (column 7 lines 1-3).

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11. Referring to claim 42 Whitt et al. teach an apparatus wherein the controller is adapted to apply a plurality of different pressure levels during a single measurement round (column 6 lines 24-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the measuring unit of Raines et al. to include a controller adapted to apply a plurality of pressure in order to account for the compliance of the cuff (Whitt et al. column 7 lines 14-41).

12. Referring to 43 Whitt et al. teach an apparatus wherein the controller is adapted to apply a continuously changing pressure (column 6 lines 24-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the controller of Raines et al. to include a continuously changing pressure similar to that of Whitt et al. in order to perform more accurate measurements.

13. Referring to claim 56 Raines et al. teach an apparatus wherein the measurement cuff is further adapted to apply a stimulus to the artery (column 9 lines 2-3). The stimulus being an occlusion for a five-minute time period.

14. Referring to claim 57 Raines et al. teach an apparatus wherein the measurement cuff is adapted to apply the stimulus by occlusion of a blood vessel (column 9 lines 2-3).

15. Referring to claim 59 Raines et al. teach an apparatus wherein the controller is adapted to restrict the flow of blood through the artery for at least 3 minutes using the measurement cuff (column 9 lines 2-3).

16. Claims 30, 36, 37, 62-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines et al. in view of Djordjevich et al. (US Patent No. 4562843). Raines et al. as described above teach all of the limitations of the claims except an

apparatus comprising a measuring unit wherein the value of the parameter is related to the cross sectional area of the artery. Djordjeovich et al. teach a measuring unit wherein the value of the parameter is related to the cross sectional area of the artery (column 5 lines 20-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the measuring unit of Raines et al. to include a parameter related to cross sectional area of the artery in view of the teachings of Djordjeovich in order to provide improved patient monitoring.

17. Referring to claim 36 Djordjeovich et al. teach a measuring unit which is adapted to measure a bio-impedance (column 20 lines 60-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the measuring unit of Raines et al. to include an impedance measurement similar to that of Djordjeovich et al. since the cross sectional area of the vessel is inversely proportional to the impedance measurement (Djordeovich et al. column 20 lines 60-63).

18. Referring to claim 37 Djordjeovich et al. further teach the measurement unit to include disposable electrodes ((column 10 lines 53-57). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the measurement unit to include disposable electrodes similar to that of Djordjeovich et al. in order to prevent cross contamination among patients.

19. Referring to claim 62 Djordjeovich et al. teach an apparatus wherein the controller is adapted to apply pressure to the cuff and to measure impedance through the measurement unit, substantially concurrently (column 12 line 3-column 13 line 32). It would have been obvious to one of ordinary skill in the art at the time of the invention to

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measure impedance concurrently with the blood pressure in order to determine the desired hemodynamic characteristics (column 13 lines 2-5).

20. Referring to claim 63 Djordjeovich et al. teach an apparatus wherein the measurement unit is comprised of at least four electrodes when sensing bio-impedance (column 12 lines 4-14).

21. Referring to claim 64 Djordjeovich et al. teach an apparatus wherein the measurement unit comprises an alternating current source and an alternating voltage measurement unit (column 10 lines 53-68).

22. Referring to claim 66 Raines et al. fail to teach a controller adapted to determine a blood pressure responsive to impedance measurements. Djordjeovich et al. teach an apparatus wherein the controller is adapted to determine a blood pressure of the patient responsive to the impedance measurements (column 12 line 52-column 13 line 32). It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt a controller similar to that of Raines et al. to determine a blood pressure responsive to impedance measurements similar to that of Djordevich et al. in order to determine the desired hemodynamic characteristics (column 13 lines 2-5).

23. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines et al. in view of Whitt et al. and further in view of Sharrock (PGPUB US 2003/0040675). Raines et al. and Whitt et al. fail to teach a disposable cuff. Sharrock teach the use of a disposable cuff (page 2 paragraph 0015). It would have been obvious to one of ordinary skill in the art at the time of the invention modify the apparatus of Raines to

include a disposable cuff similar to that of Sharrock in order to obtain infection control (page 2 paragraph 0015).

Allowable Subject Matter

24. Claims 32, 35, 40, 44-46, 58, 60, 61, 65, 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

25. Claim 32 defines over prior art of record because prior art of record fail to teach or fairly suggest an apparatus as claimed by the applicant wherein the measurement cuff includes a motor adapted to pull a strap in order to apply pressure.

26. Claim 35 defines over prior art of record because prior art of record fail to teach or fairly suggest a measurement cuff as claimed by the applicant adapted to apply a local pressure, which does not substantially affect other blood vessels in a same limb as the artery.

27. Claim 40 defines over prior art of record because prior art of record fail to teach or fairly suggest a controller as claimed by the applicant, which is adapted to apply a pressure such that the artery collapses in diastole and recuperates in systole.

28. Claims 44 and 45 define over prior art of record because prior art of record fail to teach or fairly suggest a processor as claimed by the applicant adapted to calculate a change in the cross-sectional area of the artery over a single cardiac cycle.

29. Claim 46 defines over prior art of record because prior art of record fail to teach or fairly suggest a processor as claimed by the applicant adapted to estimate an

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envelope of the measured parameter values and find a maximal parameter value difference from the envelope.

30. Claim 58 defines over the prior art of record because prior art of record fail to teach or fairly suggest an apparatus as claimed by the applicant comprising a second measurement cuff.

31. Claims 60-61 and 65 define over prior art of record because prior art of record fail to teach or fairly suggest a controller or a processor as claimed by the applicant that provides a score indicative of the endothelial function of the artery based on the values determined by the measurement unit in the at least two measurement rounds.

32. Claim 67 defines over prior art of record because prior art of record fail to teach or fairly suggest an apparatus as claimed by the applicant wherein the controller is adapted to administer at least one drug to a patient as a stimulus.


Conclusion

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

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